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(54) Title: DELIVERY OF A SACRIFICIAL SUBSTRATE TO INHIBIT PROTEASE PERMEATION INTO SKIN

(57) Abstract: The present invention relates to a topical delivery system effective in depositing a thin, tenacious and substantially continuous coating of a sacrificial substrate on skin by an aqueous emulsion mediated dissolution of protein from a sheet material with subsequent transfer and deposition onto the skin. Coatings of sacrificial substrate on skin resist removal, thereby providing a protective barrier against chemically- and biochemically-induced skin damage. The treatment composition also provides a vehicle for administering an effective dose of an active agent to the skin surface.

DELIVERY OF A SACRIFICIAL SUBSTRATE TO INHIBIT PROTEASE PERMEATION INTO SKIN

FIELD OF THE INVENTION

This invention relates to the use of a treatment composition to enhance skin health. The treatment composition includes a surfactant and a sacrificial substrate that can be applied to a sheet material such as a nonwoven web, such that the composition will impart adequate fluid handling properties to the sheet material and will subsequently
5 be transferred to the skin. The treatment composition may further be used as a vehicle to deliver active agents to the skin.

BACKGROUND OF THE INVENTION

The skin is naturally an excellent barrier to the penetration of many foreign substances. From time-to-time, the natural ability of the skin to protect is compromised by
10 external factors including abrasions, irritants and the like. Attempts have been made in recent years to promote skin health through the use of creams, lotions and fiber products containing additives in order to maintain the skin health. Effective delivery of compositions via fiber products that can enhance or prevent damage to the underlying protective barrier of skin is not yet known.

15 Enhancing skin health has many advantages including: 1) protecting the skin and maintaining the skin in a moist state, essentially free from chapping or irritation, 2) pH buffering and barrier enhancement to maintain or enhance such base properties of skin, 3) inhibition of irritants that are suspected to promote irritant or allergic contact dermatitis, and 4) maintaining the lubricity of skin.

20 The permeability of the skin to a foreign substance is influenced by a combination of physico-chemical parameters for both the object and the vehicle, if applicable, that

delivers the object. Maintaining health of the skin and its underlying barrier properties requires optimal physico-chemical properties of the skin.

When skin is attacked by proteases, the stratum corneum layer of the skin is compromised and the skin subsequently becomes inflamed. There are currently several known lotions and creams available that treat inflammation once it has occurred. To the user, however, discomfort has already been transpired because of the inflammation. A need still exists for a method and combination of preventing skin irritation rather than treating it.

There is a need for a treatment combination for use with a sheet material that is capable of delivering a thin, tenacious, substantially continuous film of the sacrificial substrate to the skin that can prevent or reduce skin irritation, maintain pH, and maintain skin hydration and lubrication. The combination of the instant invention fulfills this need. Additionally, while skin wellness additives are known, other compositions have had the undesired side effect of reducing wettability, or the fluid intake rate, of the sheet material. There remains a need for a treatment composition for application and use with a sheet material that will not adversely affect fluid properties of the sheet material, e.g. fast and sustainable fluid intake rate.

20

SUMMARY OF THE INVENTION

The present invention relates to a topical delivery system effective in depositing a thin, tenacious and substantially continuous coating of a sacrificial substrate, e.g. protein or protein hydrolysate, on skin by an aqueous emulsion mediated dissolution of the sacrificial substrate from a sheet material with subsequent transfer and deposition onto the skin. Coatings of the sacrificial substrate on skin resist removal, thereby providing a protective barrier against chemically- and biochemically-induced skin damage. The

treatment combination also provides a vehicle for administering an effective dose of a active agent to the skin surface.

BRIEF DESCRIPTION OF THE DRAWINGS

The file of this patent contains at least one drawing executed in color. Copies of this
5 patent with color drawings will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

FIG. 1 is a schematic illustration of a treating process useful for application of the treatment combination of the present invention to one or both sides of the sheet material.

FIG. 2 is a partially cut-away top plan view of an exemplary personal care product, in
10 this case a diaper, which may utilize the treated sheet material according to the present invention.

FIG. 3 is a 200X optical microscopy (Brightfield and Fluorescent Image) of a substrate treated with a treatment composition according to an aspect of the present invention.

15 FIG. 4 is a 200X optical microscopy (Fluorescent Image) showing the liquid mediated transfer of the treatment composition from the treated substrate and dissolving in the liquid.

FIG. 5 is a 200X optical microscopy (Fluorescent Image) of skin that has been treated with a treatment composition including liquid mediated transfer of the composition
20 to the skin, wherein a silk protein has been labeled with a fluorescent dye to show the transfer of a thin, tenacious, substantially continuous film to the skin.

FIG. 6 is a 100X optical microscopy (Brightfield and Fluorescent Image) of skin that has been treated in accordance with the prior art in that the treatment composition has been transferred to the skin by mechanical transfer, wherein a silk protein has been
25 labeled with a fluorescent dye to show the transfer of a substantially discontinuous film to the skin.

FIG. 7 is a graph comparing inhibition of proteolytic activity by wheat proteins in accordance with the present invention.

FIG. 8 is a graph comparing inhibition of proteolytic activity by soy protein hydrolysate in accordance with the present invention.

5 FIG. 9 is a graph comparing inhibition of proteolytic activity by elastin protein hydrolysate in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Compositions and methods are provided by the present invention for topical administration of sacrificial substrates to the skin of mammals, especially humans, to protect the skin by preserving and restoring the natural integrity of the skin. As used
10 herein, the term "sacrificial substrate" means the substitute protein that will be cleaved by proteases, usually preferentially, over the proteins in the stratum corneum layer of the skin. The present invention provides for depositing a sacrificial substrate, e.g. a protective protein, from a sheet material that is able to control the release of the sacrificial substrate
15 to the surface of the skin. The sacrificial substrate acts as a protectorant that is capable of inhibiting the activity of irritants to the skin, maintaining the pH of the skin, and maintaining skin hydration and lubrication. Pancreatic digestive enzymes that are expelled by the body with feces have been implicated to induce skin inflammation (Anderson, P.H., Bucher, A.P., Saees, II, Lee, P.C., Davis, J.A., and Maibach, H.I., Faecal
20 enzymes: in vivo skin irritation. *Contact Dermatitis* 1994; 30, 152-158). When the feces, including these enzymes, contact the skin, the skin becomes irritated. It has been found that, in fact, proteases, e.g. fecal and urine proteases, cleave proteins found in the stratum corneum layer of the skin, thereby breaking down the natural protective barrier of the skin, and leaving the skin susceptible to irritation by enzymes. The treatment
25 composition of the present invention is designed to form a thin, tenacious, substantially continuous film over the skin to inhibit, or at least minimize, the effect of such fecal irritants.

The treatment composition of the present invention includes a surfactant and a sacrificial substrate. Preferably, the treatment composition is prepared as an emulsion of the surfactant and sacrificial substrate, usually as an oil-in-water (o/w) emulsion.

Examples of emulsions include aqueous emulsions of sacrificial substrates, e.g. wheat protein, and surfactants, e.g. AHCOVEL Base N-62 (hereinafter "AHCOVEL"), a mixture of sorbitan monooleate and polyethoxylated hydrogenated castor oil, manufactured by Hodgson Co. It has been found that when emulsions containing about 75 wt.% surfactant and up to about 25 wt.% sacrificial substrate at about 0.1 to 40 wt.% total solids are used, sufficient amounts of sacrificial substrate and other ingredients transfer to the skin. Preferably, the emulsions will contain between about 5 to 30 wt.% solids. These emulsions can either be applied onto a sheet material from a high-solids bath (up to 40 wt.%) or from dilute baths ranging from 0.1 wt.% to about 20 wt.%. Preferably, the emulsion will be diluted to about 0.5 wt.% to about 15 wt.%.

The concentration of the proteins in these formulations can vary widely, and will be selected primarily by intended use, viscosity, etc., in accordance with the particular indication and mode of administration selected. Actual methods of preparing such dosage forms are known, or will be apparent, to those skilled in this art; for example, see Remington's Pharmaceutical Science, Mack Publishing Company, Easton, Pa., 19th ed., 1995, which is incorporated herein by reference. The composition or formulation to be transferred to the skin, in any event, contains a quantity of the sacrificial substrate sufficient to achieve the desired therapeutic or prophylactic effect.

The sacrificial substrate may be chosen from one of several proteins and/or protein hydrolysates. The sacrificial substrate may be selected from, for example, keratin, collagen, elastin, gelatin, casein, albumin, fibrinogen, fibronectin, soy protein, wheat protein, corn protein, milk proteins and/or hydrolysates thereof. The critical function of the sacrificial substrate is to capture the protease before it has a chance to attack the proteins in the stratum comeum layer of the skin. In fact, the sacrificial substrate should be one

that the protease would preferentially cleave instead of the skin protein. In this way, the skin surface is never compromised and does not have an opportunity to become inflamed. Skin irritation is then preferably prevented rather than treated.

In addition, other substances may be applied in addition to the sacrificial
5 substrates, either singly or in combination with any other substance disclosed herein. These may be selected from, for example, lipids, which form a hydrophobic barrier and/or restore barrier function to the skin. Useful lipids include nonpolar, e.g. ceramides and cholesterol, and polar, cholesterol sulfate. Hydrophobic compounds and ion exchange
10 resins are additional examples of substances that may be applied with the sacrificial substrates. Examples of hydrophobic compounds include polymers, e.g. polysiloxanes, polyvinyl alcohol, mineral oil, lanolin and beeswax.

Additionally, the treatment combination may optionally include protein derivatives such as silk fibers and hydrolysate of silk fibers. The silk fibers may be used in the form of powder in preparing the emulsion or as a powder of a product obtained by washing and
15 treating the silk fibers with an acid. Preferably, silk fibers are used as a product obtained by hydrolysis with an acid, alkali or enzyme, as disclosed in U.S. Patent No. 4,839,168 to Abe et al.; U.S. Patent No. 5,009,813 to Watanabe et al., and U.S. Patent No. 5,069,898 to Goldberg, each incorporated herein by reference in its entirety.

Another silk derivative that may be employed in the composition of the present
20 invention is protein obtained from degumming raw silk, as disclosed, for example, in U.S. Patent No. 4,839,165 to Hoppe et al., incorporated herein by reference in its entirety. The principal protein obtained from the raw silk is sericin, which has an empirical formula of $C_{15}H_{25}O_3N_5$ and a molecular weight of about 323.5.

A preferred silk derivative is a mixture of two or more individual amino acids, which
25 naturally occur in silk. The principal silk amino acids are glycine, alanine, serine and tyrosine.

Another example of a silk derivative for use in the emulsion composition of the present invention is a fine powder of silk fibroin in nonfibrous or particulate form, as disclosed in U.S. Patent No. 4,233,212 to Otoi et al., incorporated herein by reference in its entirety.

5 The fine powder is produced by dissolving a degummed silk material in at least one solvent selected from, for example, an aqueous cupriethylene diamine solution, an aqueous ammonia solution of cupric hydroxide, an aqueous alkaline solution of cupric hydroxide and glycerol, an aqueous lithium bromide solution, an aqueous solution of the chloride, nitrate or thiocyanate of calcium, magnesium or zinc and an aqueous sodium
10 thiocyanate solution. The resulting fibroin solution is then dialyzed. The dialyzed aqueous silk fibroin solution, having a silk fibroin concentration of from about 3 to 20% by weight, is subjected to at least one treatment for coagulating and precipitating the silk fibroin, such as, for example, by the addition of a coagulating salt, by aeration, by coagulation at the isoelectric point, by exposure to ultrasonic waves, by agitation at high
15 shear rate and the like.

The resulting product is a silk fibroin gel, which may be incorporated directly into a treatment composition or the same may be dehydrated and dried into a powder and then dissolved in the treatment composition.

20 The silk material used to form the silk fibroin includes cocoons, raw silk, waste cocoons, raw silk waste, silk fabric waste and the like. The silk material is degummed or freed from sericin by a conventional procedure such as, for example, by washing in warm water containing a surfactant-active agent or an enzyme, and then dried. The degummed material is dissolved in the solvent and preheated to a temperature of from about 60 to 95°C, preferably of from about 70 to 85°C. Further details of the process of obtaining the
25 silk fibroin are discussed in previously referenced U.S. Patent No. 4,233,212.

Turning to the surfactants useful in the treatment composition of the present invention, the surfactant can be present in the composition in amounts of about 0.3 to

about 50% by weight, preferably up to about 40% by weight, and most preferably up to about 35% by weight, of the composition and provides superior fluid handling performance, skin protection and mildness to human skin. Useful examples of the surfactant include ethoxylated hydrogenated fatty oils, monosaccharides, 5 monosaccharides derivatives, polysaccharides, polysaccharide derivatives, and combinations thereof.

Water miscible nonionic surfactants are preferred and such surfactants are commercially available. An example of such a surfactant includes AHCVEL. Additionally, Glucopon 220UP, available from Henkel Corporation, is an alkylpolyglycoside 10 having 8 to 10 carbons in the alkyl chain, and may also be used as a part of the surfactant. Other well known nonionic surfactants are the primary aliphatic alcohol ethoxylates, secondary aliphatic alcohol ethoxylates, alkylphenol ethoxylates and ethylene-oxide-propylene oxide condensates on primary alkanols, such as PLURAFACS and PLURONICS (available from BASF, Inc.) and condensates of ethylene oxide with 15 sorbitan fatty acid esters such as TWEEN (also available from Uniqema). The nonionic surfactants generally are the condensation products of an organic aliphatic or alkyl aromatic hydrophobic compound and hydrophilic ethylene oxide group. Practically any hydrophobic compound having a carboxy, hydroxy, amido, or amino group with a free hydrogen attached to the nitrogen can be condensed with ethylene oxide or with the 20 polyhydration product thereof, polyethylene glycol, to form a water miscible nonionic surfactant. Other suitable surfactants include polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monostearate, polyoxyethylene sorbitan trioleate, polyoxyethylene sorbitan tristearate, and bovine lipid extract surfactant (Survanta, Ross Laboratories), a drug used to treat Acute Respiratory Distress Syndrome and Cystic 25 Fibrosis, and enzymes such as papain or pepsin which cleave protein structures.

More specifically, the nonionic surfactant may include the condensation products of a higher alcohol (e.g., an alkanol containing about 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 or

18 carbon atoms in a straight or branched chain configuration) condensed with about 5 to 30 moles of ethylene oxide. Examples include: lauryl or myristyl alcohol condensed with about 16 moles of ethylene oxide (EO); tridecanol condensed with about 6 moles of EO; myristyl alcohol condensed with about 10 moles of EO per mole of myristyl alcohol; the
5 condensation product of EO with a cut of coconut fatty alcohol containing a mixture of fatty alcohols with alkyl chains varying from 10, 11, 12, 13 or 14 carbon atoms in length and wherein the condensate contains either about 6 moles of EO per mole of total alcohol or about 9 moles of EO per mole of alcohol; and tallow alcohol ethoxylates containing 6 EO to 11 EO per mole of alcohol. Condensates of 2 to 30 moles of ethylene oxide with
10 sorbitan mono- and 3C₁₀-C₂₀ alkanolic acid esters having a HLB (hydrophilic/lipophilic balance) of about 4 to 20, preferably about 8 to 15, may also be employed as the nonionic surfactant.

Another class of surfactant compounds includes the alkyl monosaccharides, which are relatively less soluble in water than the higher alkyl polysaccharides. Alkyl
15 polysaccharides are alkyl polyglycosides having the formula SUGAR-O-R, where R is a hydrophobic group.

Compositions and methods are also provided by the present invention for topical administration of the protein concurrently with a biologically active agent that can be administered topically in a controlled manner. Examples of such substances include
20 active agents such as multivalent metal compounds including zinc salt, zinc sulfate monohydrate, and the like. These active agents are particularly useful as astringents and enzyme inhibitors. The amount of active agent may be introduced in the composition described above in the range from about 0.01% to about 10% by weight of the composition. Preferably, the active agent may be present in the amount of about 0.25%
25 to about 1% by weight of the composition.

The composition of the present invention can be in the form of an oil-in-water (o/w) emulsion or after dilution with water, with the essential ingredients being water, surfactant, and/or co-surfactant.

Because the composition as prepared is an aqueous liquid formulation and since
5 no particular mixing is required to form the o/w emulsion, the composition is easily prepared simply by combining all the ingredients in a suitable vessel or container. The order of mixing the ingredients is not particularly important and generally the various ingredients can be added sequentially or all at once or in the form of aqueous emulsions of each or all of the primary surfactants and co-surfactants can be separately prepared
10 and combined with each other. It is important to note that emulsions of, for instance, organic acid emulsions would not be acceptable for use in the present invention, since such emulsions would be a strong skin irritant and counterproductive to the intended use of the present invention. The active agent, when present, can be added as an aqueous emulsion thereof or can be added directly. It is not necessary to use elevated
15 temperatures in the formation step and room temperature is sufficient. However, higher temperatures of up to about 180°F (82.2°C), preferably 110 to 140°F (43.3 to 60°C), can also be used.

For administration to the skin of a human or other mammal, the treatment compositions will often be sterilized or formulated to contain one or more preservatives for
20 incorporation into pharmaceutical, cosmetic or veterinary formulations. These treatment compositions can be sterilized by conventional, well-known sterilization techniques, e.g., boiling or pasteurization, without substantially adversely affecting the biological activity of the composition. The compositions may contain pharmaceutically acceptable auxiliary substances as required to approximate physiological conditions and as necessary to
25 prepare compositions for convenient administration, such as pH adjusting and buffering agents, preservatives, and delivery vehicles. Actual methods for preparing pharmaceutically administrable compounds will be known or apparent to those skilled in

the art and are described in detail in, for example, Remington's Pharmaceutical Science, supra.

Perfumes, dyes and pigments can also be incorporated into the treatment compositions of the invention. For semi-solid compositions, as would be appropriate for
5 pastes and creams intended for topical administration, the peptone-copper complexes can be provided separately or may be compounded with conventional nontoxic carriers such as, for example, aloe vera gel, squalene, glycerol stearate, polyethylene glycol, cetyl alcohol, stearic acid, and propylene glycol, among others. Such compositions may contain about 5-100% active ingredients, more preferably about 5-25%.

10 As referred to above, a unique and surprising aspect of the present invention includes the ability of the sacrificial substrate to be transferred from the sheet material to the skin. It has been found that when a fluid is introduced to the sheet material, the sacrificial substrate will dissolve in the fluid, and then fluid-mediated transfer of the sacrificial substrate to the skin occurs. In other words, the treatment composition
15 including the protein dissolves off of the sheet material into the fluid, which then deposits the thin, tenacious and substantially continuous film onto the skin. Urine is an example of a fluid that can transfer the sacrificial substrate from the sheet material to the skin. As another example, the fluid generated by the body after abrasion or injury to the skin, might provide sufficient fluid-mediated transfer of the sacrificial substrate from the sheet
20 material, in this case, a bandage or wound dressing. In general, when wetness increases, the sacrificial substrate will transfer to the skin to form a protective barrier.

In prophylactic and cosmetic applications the compositions are employed for protecting the skin from damage. Thus, the sacrificial substrates or sacrificial substrates and active agents are administered to a host under conditions which protect the integrity
25 of the skin, maintains physiological pH, skin hydration and lubrication. In these uses the precise amounts again depend on the amount of protection desired and the extent and conditions under which the skin is exposed to potentially damaging conditions, such as

those caused by fecal proteases, urine, or other irritating substances. They can generally range from about 0.1 mg to about 10 mg per day per square centimeter of skin. Single or multiple administrations of the compositions can be carried out daily or over a prolonged period of time.

5 The sacrificial substrates of the present invention may be administered to the skin in relatively large amounts without serious side effects, although indiscriminate use may produce irritation of the skin. In instances where the compositions are administered prophylactically to inhibit oxidative or biochemical damage to the skin or to those suffering from only mild skin damage, irritation or inflammation of the skin, the dose may be
10 adjusted to lower maintenance levels.

 The treatment composition providing skin protection and enhanced repair of the present invention, including pharmaceutical compositions, may be administered alone or as combination or adjunct therapy or prophylaxis. For example, the treatment compositions can be used in combination with other skin protective factors or those found
15 to improve other aspects of protection or healing. In this manner a synergistic effect may be attained that yields a clinical efficacy greater than that realized with any single factor.

 Further, while the compositions described herein stimulate a spectrum of skin protective processes, skin can differ considerably in its properties, leading one to utilize a combination of a composition described herein and another compound or factor.

20 Factors with reported healing properties which can be included with the treatment compositions for use in protective/healing formulations and methods of the present invention include, for example, epidermal growth factor, fibroblast growth factor, nerve growth factor, transforming growth factors, angiogenic growth factors, heparin, fibronectin, fibrin, platelet-derived growth factor, enzymatic superoxide dismutase, extracts of blood or
25 factors from the blood, and other similar factors.

 Sheet materials particularly adapted to receive exudate liquids such as menses, mucous, blood products, feces, and others, which will be apparent to those skilled in the

art, are useful in the present invention. As used herein, the term "sheet material" refers to a material that can be a woven fabric, knit fabric, nonwoven fabric, foam, film-like material (e.g. an apertured film-like material) or paper material. Particularly useful sheet materials include infant and child care products such as disposable diapers, training pants and baby
5 wipes, feminine hygiene products such as menses absorbing devices like sanitary napkins and tampons, bandages, and incontinent products, for example. In accordance with the invention the sheet material is often normally hydrophobic and contains the treatment combination placed so as to contact the exudate. Many polymers useful in the formation of nonwoven webs, e.g. polypropylene, are hydrophobic and highly apolar. As is known to
10 those skilled in the art, many of the sacrificial substrates used herein are highly hydrophilic, hence polar. There is, therefore, no affinity between the sheet material and the sacrificial substrate, making it difficult to apply the sacrificial substrate to the sheet material. The unique combination of the sacrificial substrates with the surfactants of the present invention overcomes this lack of affinity. In other words, the surfactant serves as
15 a medium to carry the sacrificial substrate for application to the sheet material. As would be understood by those skilled in the art, some synthetic fibers, such as nylon, are hydrophilic, and would not therefore have this particular problem addressed with the present invention.

Advantageously the sheet material is a nonwoven web and may be, for example, a
20 spunbond, meltblown, coformed or bonded carded web. Additional sheet materials which can be used include foams and films that are fibrillated, apertured or otherwise treated to have fiber-like properties as well as laminates of these and/or nonwoven webs. Depending on the particular application, the sheet material may be used as a body contact liner, a distribution layer between a liner and an absorbent layer, an absorbent
25 layer, or in more than one of these layers.

As used herein the term "nonwoven fabric or web" means a web having a structure of individual fibers or threads, which are interlaid, but not in a regular or identifiable manner

as in a knitted fabric. The term also includes individual filaments and strands, yarns or tows as well as foams and films that have been fibrillated, apertured, or otherwise treated to impart fabric-like properties. Nonwoven fabrics or webs have been formed from many processes such as for example, meltblowing processes, spunbonding processes, cofforming
5 processes and bonded carded web processes. The basis weight of nonwoven fabrics is usually expressed in ounces of material per square yard (osy) or grams per square meter (gsm) and the fiber diameters useful are usually expressed in microns. (Note that to convert from osy to gsm, multiply osy by 33.91).

As used herein the term "microfibers" means small diameter fibers having an
10 average diameter not greater than about 50 microns, for example, having an average diameter of from about 0.5 microns to about 50 microns, or more particularly, microfibers may have an average diameter of from about 2 microns to about 40 microns. Another frequently used expression of fiber diameter is denier, which is defined as grams per 9000 meters of a fiber and may be calculated as fiber diameter in microns squared, multiplied by
15 the density in grams/cc, multiplied by 0.00707. A lower denier indicates a finer fiber and a higher denier indicates a thicker or heavier fiber. For example, the diameter of a polypropylene fiber given as 15 microns may be converted to denier by squaring, multiplying the result by 0.89 g/cc and multiplying by 0.00707. Thus, a 15 micron polypropylene fiber has a denier of about 1.42 ($15^2 \times 0.89 \times 0.00707 = 1.415$). Outside the United States the
20 unit of measurement is more commonly the "tex", which is defined as the grams per kilometer of fiber. Tex may be calculated as denier/9.

As used herein the term "spunbonded fibers" refers to small diameter fibers which are formed by extruding molten thermoplastic material as filaments from a plurality of fine, usually circular capillaries of a spinneret with the diameter of the extruded filaments then
25 being rapidly reduced as, for example, described in U.S. Patent No. 4,340,563 to Appel et al., and U.S. Patent No. 3,692,618 to Dorschner et al., U.S. Patent No. 3,802,817 to Matsuki et al., U.S. Patent Nos. 3,338,992 and 3,341,394 to Kinney, U.S. Patent No. 3,502,763 to

Hartmann, U.S. Patent No. 3,502,538 to Levy, and U.S. Patent No. 3,542,615 to Dobo et al.

Spunbond fibers are quenched and generally not tacky when they are deposited onto a collecting surface and usually subjected to a separate bonding step. Spunbond fibers are generally continuous and have average diameters frequently larger than 7 microns, more particularly, between about 10 and 20 microns.

As used herein the term "meltblown fibers" means fibers formed by extruding a molten thermoplastic material through a plurality of fine, usually circular, die capillaries as molten threads or filaments into converging high velocity, usually heated, gas (e.g. air) streams which attenuate the filaments of molten thermoplastic material to reduce their diameter, which may be to microfiber diameter. Thereafter, the meltblown fibers are carried by the high velocity gas stream and are deposited on a collecting surface often while still tacky to form a web of randomly dispersed meltblown fibers. Such a process is disclosed, for example, in U.S. Patent No. 3,849,241 to Butin. Meltblown fibers are microfibers which are usually continuous, but which may also be discontinuous, and are generally smaller than 10 microns in average diameter.

The sheet material of the present invention may also include a bonded carded web. As used herein "bonded carded webs" or "BCW" refers to nonwoven webs formed by carding processes as are known to those skilled in the art and further described, for example, in coassigned U.S. Patent No. 4,488,928 to Alikhan and Schmidt which is incorporated herein by reference in its entirety. Briefly, carding processes involve starting with a blend of, for example, staple fibers with bonding fibers or other bonding components in a bulky batt that is combed or otherwise treated to provide a generally uniform basis weight. This web is heated or otherwise treated to activate the adhesive component resulting in an integrated, usually lofty nonwoven material.

As would be understood by one of ordinary skill in the art, such nonwoven webs may be formed from different types of polymers, which may be extruded as monocomponent fibers, biconstituent fibers and/or conjugate fibers (multi- and bicomponent fibers) filaments.

Biconstituent fibers are sometimes also referred to as multiconstituent fibers. Fibers of this general type are discussed in, for example, U.S. Patent No. 5,108,827 to Gessner.

Bicomponent and biconstituent fibers are also discussed in the textbook Polymer Blends and Composites by John A. Manson and Leslie H. Sperling, copyright 1976 by Plenum

5 Press, a division of Plenum Publishing Corporation of New York, ISBN 0-306-30831-2, at pages 273 through 277. Conjugate fibers are taught in U.S. Patent No. 5,108,820 to Kaneko et al., U.S. Patent No. 5,336,552 to Strack et al., and U.S. Patent No. 5,382,400 to Pike et al.

Small amounts of additives may be added for color, anti-static properties, lubrication,
10 hydrophilicity, antibacterial, antimold, deodorizing effect, and the like. These additives, e.g. titanium dioxide for color and chitosan as an antibacterial, are generally present in an amount less than 5 weight percent and more typically about 2 weight percent.

As used herein, the term "personal care product" includes diapers, training pants, swim pants, absorbent underpants, adult incontinence products, sanitary wipes, feminine
15 hygiene products such as sanitary napkins and tampons, wound dressings and bandages.

As used herein, the term "hydrophilic" means that the polymeric material has a surface free energy such that the polymeric material is wettable by an aqueous medium, i.e. a liquid medium of which water is a major component. The term "hydrophobic" includes those materials that are not hydrophilic as defined. Hydrophobic materials may be treated
20 internally or externally with surfactants and the like to render them hydrophilic.

The sheet material of the present invention may be a multilayer laminate. An example of a multilayer laminate is an embodiment wherein some of the layers are spunbond and some meltblown such as a spunbond/meltblown/spunbond (SMS) laminate as disclosed in U.S. Patent No. 4,041,203 to Brock et al., U.S. Patent No. 5,169,706 to
25 Collier, et al, and U.S. Patent No. 4,374,888 to Bornslaeger. Such sheet materials usually have a basis weight of from about 0.1 to 12 osy (6 to 400 gsm), or more particularly from about 0.75 to about 3 osy.

Spunbond nonwoven fabrics are generally bonded in some manner as they are produced in order to give them sufficient structural integrity to withstand the rigors of further processing into a finished product. Bonding can be accomplished in a number of ways such as hydroentanglement, needling, ultrasonic bonding, adhesive bonding, stitchbonding, 5 through-air bonding and thermal bonding such as calendering.

The addition of the treatment combination to the sheet material may be accomplished by conventional means such as spraying, coating, dipping and the like although the use of high solids spray is advantageous in cases where drying and/or compression is desired to be minimized. The individual components of the treatment 10 combination, the sacrificial substrate and the surfactant, may be added to the sheet material either singly or by first preparing a composition of the components and then applying the composition to the substrate. The amount of the treatment composition used will depend on the particular end use as well as factors such as basis weight and porosity of the sheet material. Referring to FIG. 1, an exemplary process will be described for 15 application to one or both sides of a traveling sheet material. It will be appreciated by those skilled in the art that the invention is equally applicable to inline treatment or a separate, offline treatment step. Sheet material 12, for example a spunbond or meltblown nonwoven web is directed over support rolls 15,17 to a treating station including rotary spray heads 22 for application to one side 14 of web 12. An optional treating station (shown in phantom) 20 which may include rotary spray heads 18 can also be used to apply to opposite side 23 of sheet material 12. Each treatment station receives a supply of treatment composition 30 from a reservoir (not shown). The treated sheet material may then be dried if needed by passing over dryer cans 25 or other drying means and then wound as a roll or converted to the use for which it is intended. Alternative drying means include ovens, through air dryers, 25 infra red dryers, air blowers, and the like.

As referred to above, a unique and surprising aspect of the present invention includes the ability of the treatment composition to be transferred from the sheet material

to the skin. It has been found that when a liquid is introduced to the sheet material, the treatment composition will dissolve in the liquid, and then liquid-mediated transfer of the treatment composition to the skin occurs. In other words, the treatment composition including the sacrificial substrate dissolves off of the sheet material into the liquid, which
5 then deposits the thin, tenacious and substantially continuous film onto the skin. Urine is an example of a liquid that can transfer the treatment composition from the sheet material to the skin. As another example, the liquid generated by the body after abrasion or injury to the skin, might provide sufficient liquid-mediated transfer of the treatment composition from the sheet material, in this case, a bandage or wound dressing. In general, when
10 wetness increases, the treatment composition will transfer to the skin to form a protective barrier.

An exemplary article 80, in this case a diaper, is shown in FIG. 2. Referring to FIG. 2, most such personal care absorbent articles 80 include a liquid permeable top sheet or liner 82, a barrier back sheet or outercover 84 and an absorbent core 86 disposed
15 between and contained by the top sheet 82 and back sheet 84. Articles 80, such as diapers, may also include some type of fastening means 88 such as adhesive fastening tapes or mechanical hook and loop type fasteners to maintain the garment in place on the wearer. The sheet material 12 may be used to form various portions of the article including, but not limited to the top sheet or liner 82.

20 The following examples are offered by way of illustration, not by way of limitation.

EXAMPLES

The compositions of the present invention were formed by creating an emulsion (or microemulsion) with water as the carrier liquid. Aqueous emulsions of proteins as the sacrificial substrate, AHCVEL, as the surfactant system, and zinc salt as the active
25 agent, were prepared. The stable emulsions were diluted to about a 5% by weight emulsion and applied to the surface of a polyolefin nonwoven liner fabric in amounts as shown below, via a saturation dip and squeeze process as described in more detail below.

The fabrics were then tested for fluid intake rate, softness, skin transfer, skin barrier, anti-inflammatory, and the like, as describe in more detail below.

Fluid Intake Rate: This test is identified as Fluid Strikethrough EDANA 150.1-90 and measures the time taken for a known volume of liquid (simulated urine) applied to the surface of a nonwoven test sample in contact with an underlying absorbent pad to pass through the nonwoven. In general, a 50 ml burette is positioned on a ring stand with the tip inside a funnel. A standard absorbent pad of 5 plies of specified filter paper (482% absorbency) is placed on an acrylic glass base plate below the funnel, and a nonwoven sample is placed on top of the absorbent. An acrylic glass strike-through plate 25 mm thick and weighing 500 g is placed over the sample with the cavity centered 5 mm below the funnel. The burette is filled with liquid, keeping the funnel closed, and a quantity of the liquid (e.g., 5 ml or 10 ml) is run into the funnel. The 5 ml or 10 ml is allowed to discharge starting a timer which stops when the liquid has penetrated into the pad and fallen below a set of electrodes, and the elapsed time is recorded. The liquid used was Blood Bank Saline, available from Stephens Scientific Co., Catalog No. 8504.

Softness Test: Although a specific softness test was not conducted, each of the samples prepared were noted to have a "soft hand", and would be suitable for use in articles as described herein.

Skin Transfer Test: A silk protein was labeled with the fluorescent dye, Texas Red (TR), according to the procedure suggested by Molecular Probes, Inc., Eugene OR (Texas Red protein labeling kit F-6162). A 4.5 wt.% solution of protein, 200uL, was reacted with 100uL of a 5mg/mL solution of Texas Red succinimide in dimethylsulfoxide for 1 hour. The thus labeled protein was isolated via gel chromatography with centrifugation for 3 minutes at 1100 x gravity.

Solutions of AHCOVEL containing a mixture of TR labeled and unlabelled protein was used to treat a sheet material of 0.6 osy polypropylene spunbond nonwoven web, prepared as a diaper liner according to the procedure described. Fluorescent microscopy

using a high pressure Hg lamp with excitation and emission bandpass filters of 595nm and 615nm, respectively, confirmed the presence of the labeled protein on the sheet material. FIG. 3 is a 200X optical microscopy (Brightfield and Fluorescent Image) of the sheet material treated with the treatment composition according to an aspect of the present invention. The untreated sheet material showed no significant fluorescence, (not shown).

Upon exposing the treated sheet material to water, intense fluorescence, characteristic of TR, could be detected in solution, suggesting solubility of the labeled protein into the wetting media. The protein was removed from the sheet material due to its solubility in water. FIG. 4 is a 200X optical microscopy (Fluorescent Image) showing this liquid mediated transfer of the treatment composition from the treated sheet material and dissolving in the liquid.

Transfer of the labeled protein from the treated sheet material to the skin was verified by the following procedure. A 1 cm² square of treated sheet material was secured to the volar forearm with adhesive tape. A majority of the area of the sheet material was not covered with tape, which was placed only on the perimeter to secure the sheet material to the arm. The sheet material was subsequently wetted with 300uL of water. After several minutes, the sheet material was removed from the arm, and the stratum corneum previously covered by the material was tape stripped with Desquame tape to remove superficial layers of skin for fluorescent microscopic analysis. Microscopy at 100x and 200x clearly revealed intense fluorescence associated with the TR labeled protein, thus confirming that transfer from the sheet material to the skin, mediated by wetting, was conclusive. FIG. 5 shows the thin, tenacious, substantially continuous film of protein that was applied to the skin by means of the present invention. The morphology of the resulting protein coating was consistent with a thin, tenacious, substantially continuous film of the protein on the corneocytes of the forearm. FIG. 6, on the other hand, shows

the variability of application of the protein by means of mechanical transfer described in the prior art.

The fabrics were then tested for topical delivery of the zinc salt using excised skins in modified FRANZ diffusion cells. The amount of zinc accumulating and penetrating the skin was determined over a 36 hour period. The accumulation of zinc was determined to be 1311 $\mu\text{g/g}$ dry weight of skin, while the penetration was measured to be 3.2 $\mu\text{g/cm}^2/\text{hr}$.

Skin Barrier Test: Uniformity of the barrier film on the skin as shown in FIG. 5 was indicative of good barrier properties.

Anti-inflammatory: The effect of proteins to inhibit the hydrolysis of a model peptide substrate by a fecal extract, (serine protease - trypsin), was determined. In addition, the ability of a protein to reduce a fecal extract-elicited pro-inflammatory response in EpiDerm™ was measured. The protein applied to a material was placed on the EpiDerm™ sample, both before and after application of the fecal irritant. The release of a pro-inflammatory signaling molecule Interleukin-1 alpha, was compared to that of the control not containing the protein.

The protein extract and the protein hydrolysates inhibited trypsin activity in a dose-dependent manner. Plots of the data for the examples which follow are shown in FIGs. 7-9, which are graphs showing how the percent of proteolytic activity was hampered with addition of the protein and hydrolysates. This data suggests that application of these sacrificial substrates to the skin has the potential to mitigate diaper rash.

Inhibition of the Proteolytic Activity of Trypsin

Soluble wheat protein (TRITISOL, Croda, Incorporated, Parsippany, NJ), hydrolyzed soy protein (HYDROSOY 2000 S.F., also available from Croda, Inc.), and hydrolyzed elastin (CROLASTIN, Croda, Inc.) were each individually shown to inhibit the chemical reaction which has been shown to contribute to diaper rash. Serial dilutions of the neat protein and hydrolysates were performed with water as the diluent. Protein

concentrations were determined for each sample using the Macro BCA Protein Assay Reagent Kit (Pierce, Rockford, IL).

A working solution of trypsin from porcine pancreas (Sigma Chemical Co., St. Louis, MO) was prepared from a 5 mg/ml stock solution stored in 50 mM NaOAc, pH 5.5, and 0.15 M NaCl at -80°C . The trypsin was diluted in 100 mM Tris-HCl, pH 8.0, to 6 ng/ml just prior to starting the reaction to limit autoproteolysis.

The protein extract and hydrolysates (20 μL) were added to wells of a 96 white plate (Dynex, Chantilly, VA) containing 100 μL of 6 ng/ml trypsin. The reaction was initiated with the addition of 80 μL of a 62.5 μM solution of a fluorescently-labeled trypsin peptide substrate (Boc-Gln-Ala-Arg-AMC HCl) (BACHEM California, Incorporated (Torrance, CA)) prepared in 100 mM Tris-HCl, pH 8.0. Relative Fluorescence Units (RFU) were collected using the Fluroskan Ascent System (Labsystems, Incorporated, Needham Heights, MA) with excitation and emission filters of 355 and 460 nm, respectively. The reaction was run for 15 min. at room temperature and rates (RFU/min) calculated.

The wheat protein inhibited trypsin activity in a dose-dependent manner. The plot of the data is shown in FIG. 7, a graph showing how the percent of proteolytic activity was hampered with addition of the protein. Likewise, the results of the proteolytic activity inhibition of hydrolyzed soy protein and hydrolyzed elastin can be found in FIGs. 8 and 9, respectively.

20

Additional compositions useful with the sacrificial substrate:

Treatment compositions containing water, AHCOVEL (Ahcovel Base N-62, Hodgson Chemicals, NC), SERICIN, CROSILK, and zinc sulfate monohydrate (Aldrich Chemicals, WI) were prepared according to Table 1 below. For comparison purposes, a control composition was prepared containing only water and AHCOVEL.

25

Table 1 – Composition Concentrations (wt.%)

Compositions	Water	AHCOVE L	SERICIN	CROSILK 10,000	Zinc Sulfate Monohydrate
Control	80	20	-	-	-
1	69.1	20	-	10	.9
2	69.1	20	10	-	.9

Although not specifically shown in the data, silk protein emulsions, without the aid of surfactant, were applied to a sheet material. Since the protein is hydrophilic, and the sheet material is hydrophobic, the protein would not easily wet and saturate the substrate, and instead formed a bead on top of the substrate.

Treated Sheet material

Untreated polypropylene spunbond materials (basis weight of about 0.5 ounces per square yard) were used as a sheet material for the treatment compositions. The compositions of Table 1 were applied to the sheet materials by a low-solids batch treatment process. An 8" x 12" (20.32 x 30.48 cm) sample of the sheet material was first dipped in an aqueous treatment bath of known composition illustrated in Table 2 below.

Table 2 – Treatment Bath Concentration as applied to the sheet materials

Example	Composition (from Table 1)	Water	Ahcovel Base N-62	Sericin	Crosilk 10,000	Zinc Sulfate Monohydrate
1	Control	98.8	1.2			
2	Control	97	3	-	-	-
3	Control	94	6	-	-	-
4	1	98.146	1.2	-	.6	.054
5	1	97	1.942	-	.971	.087
6	1	94	3.883		1.942	.175
7	2	97	1.942	.971		.087
8	2	94	3.883	1.942	-	.175

15

The saturated samples were then nipped between two rubber rollers in a laboratory wringer, Type LW-1, No. LW-83A (Atlas Electric Devices, Chicago, IL), and subsequently dried in an oven at 60°C for about 20 minutes or until constant weight was obtained. Nip pressure was adjusted to achieve a 100% wet pick-up (%WPU). %WPU is calculated from the following equation:

$$\%WPU = [(W_w - W_d)/W_d] \times 100,$$

where:

Ww = wet weight of the nipped fabric,

Wd = dry weight of the treated fabric.

- 5 Knowing the bath concentration and the %WPU, the % Add On can be calculated from the following equation:

$$\%AddOn = (\%BathConcentration) \times (\%WPU) \div 100$$

- If, as in this example, the %WPU = 100, then the % Add-On will equal the % Bath Concentration. However, other %WPU and % Bath Concentration combinations can be
10 used to achieve similar results. Final % Add-On for each component of each example is shown in Table 3 below.

Table 3 – % Add-On for Each Example of Table 2

Example	Ahcovel Base N-62	Sericin	Crosilk 10,000	Zinc Sulfate Monohydrate
1	1.2	-	-	-
2	3	-	-	-
3	6	-	-	-
4	1.2	-	.6	.054
5	1.942	-	.971	.087
6	3.883	-	1.942	.175
7	1.942	.971	-	.087
8	3.883	1.942	-	.175

- The Fluid Intake Rate was determined for some of the examples of Table 3 as
15 shown in Table 4 below, according to the test as described above. As shown in the data, fluid-intake rates have not been adversely affected by addition of the treatment composition of the present invention, and the sheet materials,
therefore, provide adequate fluid handling properties.

Table 4 - Fluid Intake Time (sec.)

Example	Intake Time (second)				
	Insult 1	Insult 2	Insult 3	Insult 4	Insult 5
2	2.82	2.83	3.05	3.21	3.15
3	2.45	2.43	2.54	2.47	2.65
5	2.38	2.41	2.43	2.35	2.55
6	2.63	2.69	2.60	2.72	2.70
7	2.51	2.72	2.43	2.32	2.38
8	2.44	2.56	2.37	2.38	2.42

While various patents and other reference materials have been incorporated herein by reference, to the extent there is any inconsistency between incorporated material and that of this written specification, the written specification shall control. In addition, while the present invention has been described in connection with certain preferred embodiments, it is to be understood that the subject matter encompassed by way of the present invention is not to be limited to those specific embodiments. On the contrary, it is intended for the subject matter of the invention to include all alternatives, modifications and equivalents as can be included within the spirit and scope of the following claims.

We Claim:

1. A treatment combination for imparting a liquid-mediated transfer medium to a sheet material, said combination comprising a surfactant and a sacrificial substrate;
the surfactant including a compound selected from the group comprising ethoxylated hydrogenated fatty oils, monosaccharides, monosaccharide derivatives,
5 polysaccharides, polysaccharide derivatives and combinations thereof.
2. The treatment combination of Claim 1, wherein said sacrificial substrate comprises a protein, protein hydrolysate, or combinations thereof.
3. The treatment combination of Claim 2 wherein said sacrificial substrate is selected from the group comprising keratin, collagen, elastin, gelatin, casein, albumin, fibrinogen, fibronectin, soy protein, wheat protein, corn protein, milk proteins and hydrolysates thereof.
4. The treatment combination of claim 2, wherein said treatment combination further comprises lipids, hydrophobic compounds, ion exchange resins, and combinations thereof.
5. The treatment combination of claim 4, wherein said sacrificial substrate forms a barrier on the surface of the skin.
6. The treatment combination of Claim 4, wherein said sacrificial substrate inhibits pancreatic digestive enzymes.
7. The treatment combination of Claim 2, wherein said surfactant and sacrificial substrate are combined in an aqueous emulsion to form a treatment composition.

8. The treatment combination of Claim 7, wherein said aqueous emulsion is a microemulsion.

9. The treatment composition of Claim 8, wherein said surfactant and sacrificial substrate are present at a weight ratio of about 0.01-25 wt.% sacrificial substrate to about 75-99.99 wt.% surfactant.

10. The treatment composition of Claim 9, wherein said emulsion further comprises 0.1 to 40 wt.% total solids.

11. The treatment composition of Claim 10 further comprising an active agent.

12. The treatment composition of Claim 8 wherein said active agent further comprises zinc salt or zinc sulfate monohydrate.

13. A sheet material treated with a treatment combination, said treatment combination comprising a surfactant and a sacrificial substrate;

the surfactant including a compound selected from the group consisting of ethoxylated hydrogenated fatty oils, monosaccharides, monosaccharides derivatives, polysaccharides, polysaccharide derivatives, and combinations thereof,

5 wherein said surfactant is a liquid-mediated transfer medium for transfer of said sacrificial substrate from said sheet material to a wearer.

14. The sheet material of Claim 13, wherein said sacrificial substrate comprises a protein, protein hydrolysate, or combination thereof.

15. The sheet material of Claim 14 wherein said sacrificial substrate is selected from the group comprising keratin, collagen, elastin, gelatin, casein, albumin, fibrinogen, fibronectin, soy protein, wheat protein, corn protein, milk proteins and hydrolysates thereof.

16. The sheet material of claim 14, wherein said treatment combination further comprises lipids, hydrophobic compounds, ion exchange resins, and combinations thereof.

17. The sheet material of claim 13, wherein said sacrificial substrate forms a barrier on the surface of the skin.

18. The sheet material of claim 13, wherein said sacrificial substrate inhibits pancreatic digestive enzymes.

19. The sheet material of Claim 13, wherein the sheet material is selected from woven fabrics, knit fabrics, nonwoven fabrics, foams, film-like materials and paper materials.

20. The treated sheet material of Claim 19, wherein the sheet material comprises a nonwoven web.

21. The treated sheet material of Claim 20 wherein said nonwoven web is hydrophobic.

22. The treated sheet material of Claim 21, wherein said nonwoven web comprises a spunbond web, meltblown web, coformed web or bonded carded web.

23. The treated sheet material of Claim 13, wherein said sheet material comprises a multilayer laminate.

24. The treated sheet material of Claim 13, wherein the treatment combination further comprises an active agent.

25. The treatment combination of Claim 24 wherein said active agent further comprises zinc salt or zinc sulfate monohydrate.

26. The treated sheet material of Claim 13, wherein the combination is applied at a level of about 0.1-1.5% by weight surfactant relative to the basis weight of the sheet material.

27. The treated sheet material of Claim 26, wherein the combination is applied at a level of about 0.1-1.0% by weight surfactant relative to the basis weight of the sheet material.

28. The treated sheet material of Claim 27, wherein the combination is applied at a level of about 0.1-0.5% by weight surfactant relative to the basis weight of the sheet material.

29. A personal care product comprising the treated sheet material of Claim 13.

30. The personal care product of Claim 29, wherein the personal care product is selected from a diaper, training pant, absorbent underpant, adult incontinence product, sanitary wipe, feminine hygiene product, wound dressing and bandage.

31. The treatment composition of Claim 29, wherein a fluid intake rate of said sheet material is not adversely affected by addition of said treatment composition.

32. The method of transferring a thin, tenacious, substantially continuous film of protein to skin comprising:

- 10 a) providing a sheet material;
- b) applying a treatment composition to said sheet material, said composition comprising a surfactant and a protein in combination; the surfactant including a compound selected from the group consisting of ethoxylated hydrogenated fatty oils, monosaccharides, monosaccharide derivatives, polysaccharides, polysaccharide derivatives, and combinations thereof,
- 15 c) insulating said sheet material with an aqueous based liquid whereby said treatment composition dissolves in said liquid, and
- d) transferring said treatment composition from said sheet material to the skin, thereby forming a thin, tenacious, substantially continuous, film on the skin.

33. The method of Claim 32 wherein said sheet material is a hydrophobic nonwoven web.

34. The method of Claim 33, wherein the sheet material comprises a personal care product.

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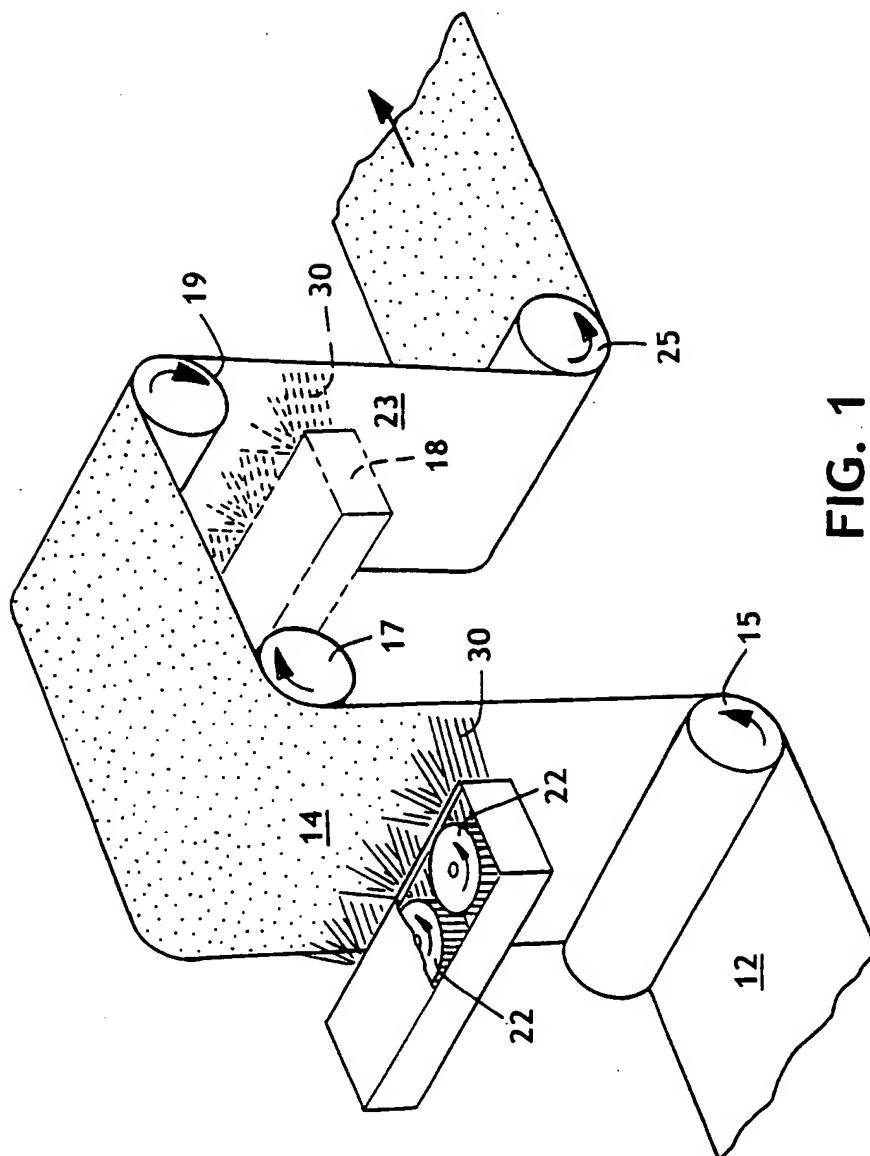


FIG. 1

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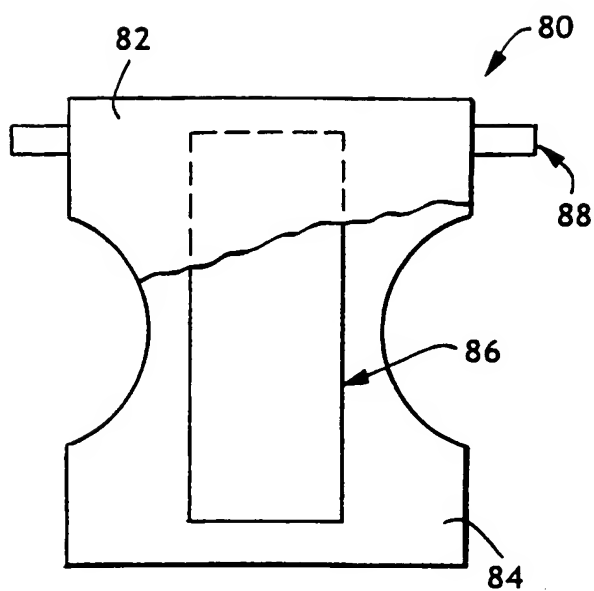


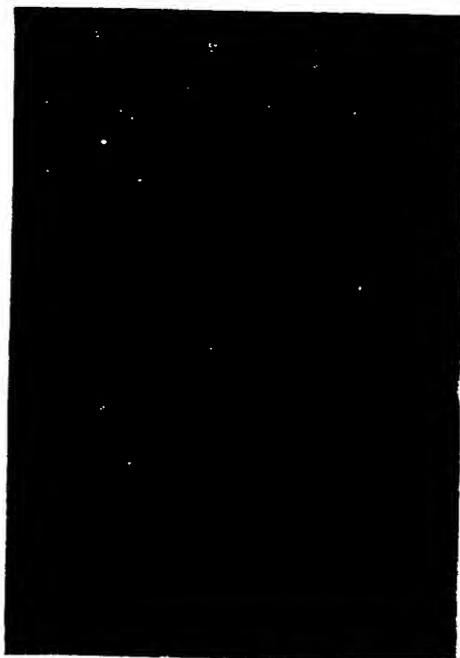
FIG. 2

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Sericin Treated Nonwoven
(a) Brightfield and (b) Fluorescent Image, both at 200x



(a)

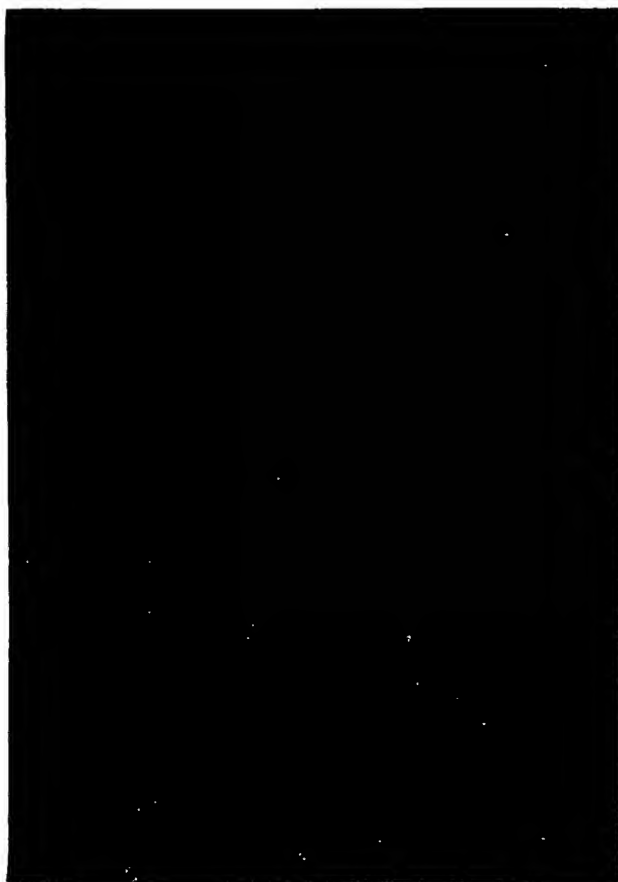


(b)

FIG. 3

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Fluid Mediated Transfer of Sericin
Dissolution of Sericin from Nonwoven into Wetting Fluid



Treated Fiber

Fluid Front Containing Fluorescent Sericin

FIG. 4

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Skin Coated with Sericin



FIG. 5

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Dry Transfer of Sericin to Skin
(a) Brightfield and (b) Fluorescent Image, both 100x



Localized Deposition of Sericin

FIG. 6

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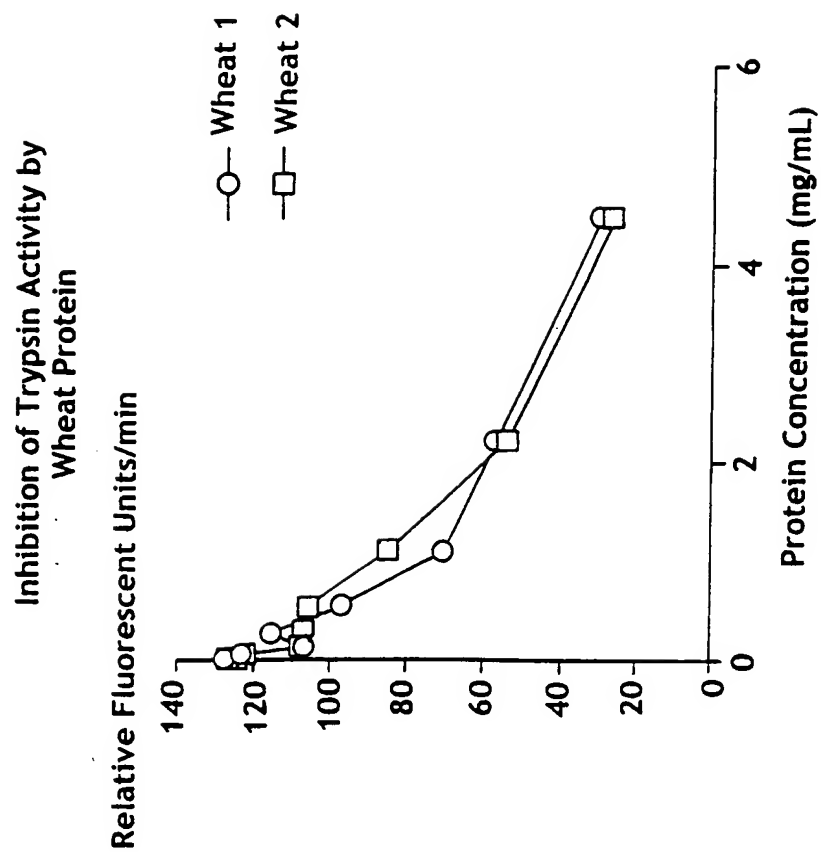


FIG. 7

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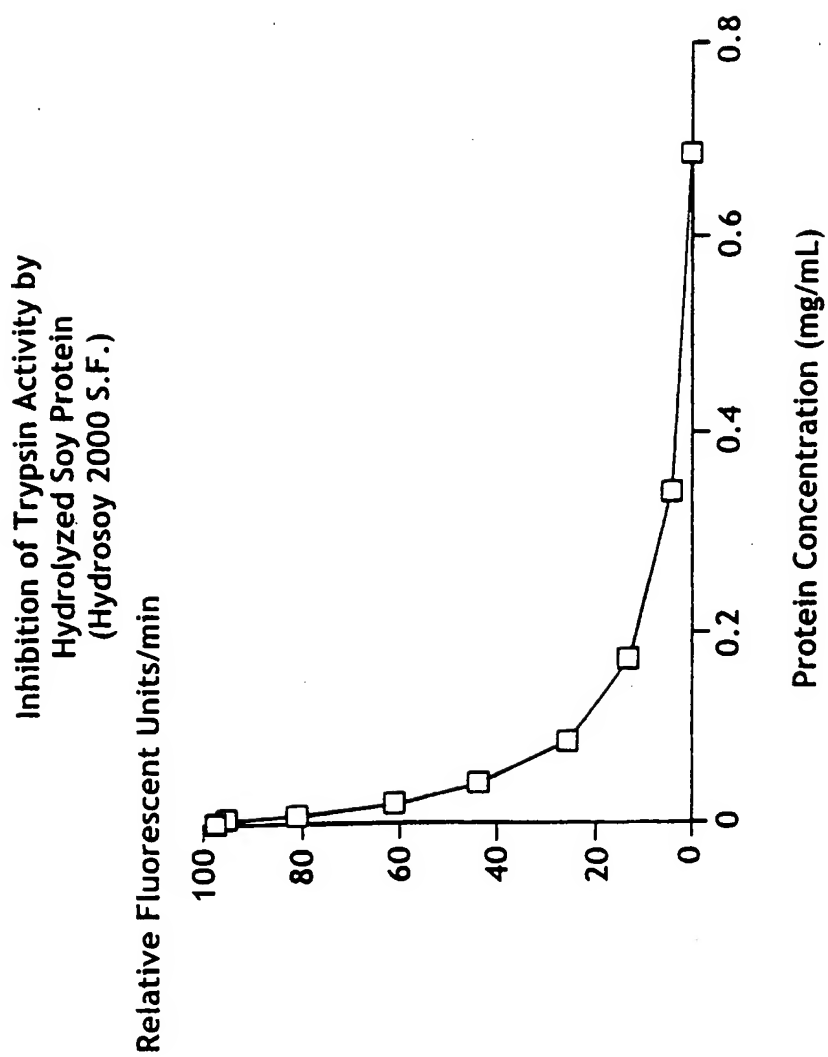
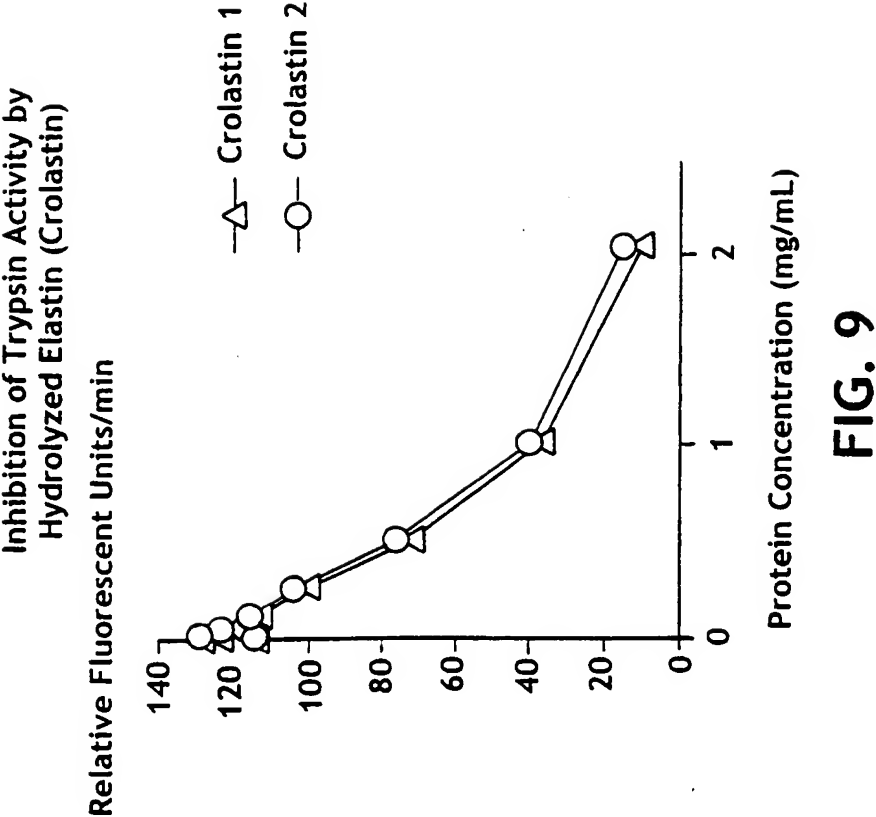


FIG. 8



INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US 00/18001

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K7/48 A61L15/22 A61F13/15 A61K9/70		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K A61L A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) CHEM ABS Data, EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 676 967 A (J. WILLIAMS ET AL.) 14 October 1997 (1997-10-14) the whole document ---	1
X	WO 99 17738 A (LAVIPHARM LABORATORIES) 15 April 1999 (1999-04-15) the whole document ---	1
A	US 5 604 200 A (D. TAYLOR-MCCORD) 18 February 1997 (1997-02-18) column 9, line 63; claim 1; example 1 ---	1
A	EP 0 312 208 A (ETHICON INC.) 19 April 1989 (1989-04-19) claims 1,16-19,23 -----	1
<input type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search 31 October 2000		Date of mailing of the international search report 10/11/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer: Glikman, J-F

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/18001

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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WO 9917738	A	15-04-1999	AU 9787398 A EP 1024788 A	27-04-1999 09-08-2000
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EP 312208	A	19-04-1989	AU 2223588 A GR 88100617 A,B JP 2000112 A MX 169808 B NZ 226171 A PT 88541 A US 5457093 A US 5705485 A US 5427778 A ZA 8806947 A	23-03-1989 22-06-1989 05-01-1990 27-07-1993 26-06-1990 31-07-1989 10-10-1995 06-01-1998 27-06-1995 30-05-1990